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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,458	11/28/2003	Leslie William Organ	BEW-005	9862
959	7590	12/11/2006	EXAMINER	
LAHIVE & COCKFIELD, LLP ONE POST OFFICE SQUARE BOSTON, MA 02109-2127			TOWA, RENE T	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/724,458

Applicant(s)

ORGAN ET AL.

Examiner

Rene Towa

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-14 and 16-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-14 and 16-24 is/are rejected.
- 7) ☒ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This Office action is responsive to an amendment filed September 19, 2006. Claims 1-2, 4-14 and 16-24 are pending. Claims 1 and 13 have been amended. Claims 3 and 15 have been cancelled. No new claim has been added.
2. The Examiner acknowledges the previous indication of allowable subject matter in claims 4-5 and 16-17. However, upon further consideration and search, Claims 4-5 and 16-17 are rejected in accordance with the rejections infra.

### ***Claim Objections***

3. Claims 1-2, 4-14 and 16-24 are objected to because of the following informalities:

In regards to claims 1 and 13, at lines 6 and 7, respectively, the limitations "the current injection electrode pair" and "the voltage measurement electrode pair" lack antecedent basis and should apparently read --a current injection electrode pair-- and --a voltage measurement electrode pair--, respectively.

In regards to claim 4, at line 1, the claim depends from a cancelled claim 3.

In regards to claim 13, at lines 7 and 8, respectively, the limitations "the current injection electrode pair" and "the voltage measurement electrode pair" lack antecedent basis and should apparently read --a current injection electrode pair-- and --a voltage measurement electrode pair--, respectively.

In regards to claim 16, at line 1, the claim depends from a cancelled claim 15.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

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4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-2, 7-11, 13-14, 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Organ (US Patent No. 6,122,544) in view of Sun et al. (US Patent No. 6,391,024).

In regards to claims 1 and 13, Organ discloses a system for diagnosing the possibility of disease in a body part, the method comprising

- providing an electrode array containing a plurality of electrodes capable of being electrically coupled to the body part;
- making an electrode assessment measurement with the electrode array;
- making a diagnosis measurement with the electrode array;
- obtaining an electrical property of the body part based on the diagnosis measurement; and
- diagnosing the possibility of disease based on the electrical property of the body part (see fig. 5; column 3/lines 29-44; columns 4-11, lines 14-46).

In regards to claims 2 and 14, Organ discloses a system wherein the plurality of electrodes includes a current injection electrode pair and an associated voltage measurement electrode pair that are applied to the body part (see column 4, lines 35-39).

In regards to claim 7, Organ teaches a system wherein the plurality of electrodes includes  $n_{cl}$  current injection electrode pairs, and  $n_{cl}$  associated voltage measurement electrode pairs, where  $n_{cl}$  is an integer greater than zero (see Column 4, lines 35-38).

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In regards to claim 8, Organ discloses a system wherein the step of making a diagnosis measurement includes applying the  $n_{cl}$  current injection electrode pairs on the body part; and applying the  $n_{cl}$  voltage measurement electrode pairs on the body part (see Column 4, lines 35-59).

In regards to claims 9-11 and 19-23, Organ discloses a system wherein the step of making a diagnosis measurement further includes

injecting a first current between a first pair of the  $n_{cl}$  current injection electrode pairs;

measuring the resultant voltage difference  $V_{1.sup.M}$  between the voltage measurement electrode pair associated with the first current injection electrode pair; and repeating the preceding two steps of injecting and measuring with the other electrode pairs until all  $n_{cl}$  voltage differences,  $\{V_1^M, V_2^M, \dots, V_{n_{cl}}^M\}$  are obtained; wherein the electrical property is impedance; wherein the step of obtaining includes using the  $n_{cl}$  voltage differences to obtain associated measured impedances,  $\{Z_1^M, Z_2^M, \dots, Z_{n_{cl}}^M\}$ , where  $Z_j^M$  is the measured impedance between the voltage electrodes associated with the  $j$ th current injection electrode pair (see Columns 6-8, lines 5-14; see columns 6-11, lines 5-53).

*Organ discloses a system, as described above, that teaches all the limitations of the claims except Organ does not explicitly teach an electrode assessment measurement that includes a bipolar measurement.*

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*However, Sun et al. disclose a system comprising an electrode assessment module 14 utilizing a bipolar measurement where one current injection electrode and one proximal voltage measurement electrode (see figs. 1 & 8c; column 3/lines 37-50).*

*It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Organ with an electrode assessment module similar to that of Sun et al. in order to measure the adequacy of contact between an electrode and biological tissue (see Sun et al., column 3/lines 28-30).*

6. Claims 12 and 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Organ ('544) in view of Sun et al. ('024) further in view of Dempsey et al (US Patent No. 5,419,337).

Organ as modified by Sun et al. discloses a system, as described above, that teaches all the limitations of the claims except Organ as modified by Sun et al. do not explicitly teach a system comprising a GUI.

However, Dempsey et al discloses a graphical user interface that includes the input of information by the user to select certain ECG strips for sampling by the computer (see Column 5, lines 13-29).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Organ with a user interface, as taught by Dempsey et al, to select certain ECG strips for sampling by the computer.

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7. Claims 4-6 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Organ ('544) in view of Sun et al. ('024) further in view of Gallup et al. (US Patent No. 5,372,141).

Organ as modified by Sun et al. discloses a system, as described above, that teaches all the limitations of the claims except Organ as modified by Sun et al. do not teach measuring a phase. However, Gallup et al. discloses a system for determining impedance comprising the steps of determining a phase (see column 7/lines 13-column 8/line 3).

Since Organ as modified by Sun et al. disclose a method wherein electrode assessment includes measurement of an impedance, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Organ as modified by Sun et al. with an impedance determining step similar to that of Gallup et al. since such a modification would amount to a design choice that would serve the same purpose of determining the impedance. Moreover, the Applicant has not disclosed that determining an impedance by way of a phase determination provides an advantage, is used for a particular purpose, or solves a stated problem.

8. Claims 4-6 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Organ ('544) in view of Sun et al. ('024) further in view of Feldman (US Patent No. 5,788,643).

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Organ as modified by Sun et al. discloses a system, as described above, that teaches all the limitations of the claims except Organ as modified by Sun et al. do not teach measuring a phase.

However, Feldman discloses a system for determining impedance comprising the steps of determining a phase (see figs. 1-2).

Since Organ as modified by Sun et al. disclose a method wherein electrode assessment includes measurement of an impedance, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Organ as modified by Sun et al. with an impedance determining step similar to that of Feldman since such a modification would amount to a design choice that would serve the same purpose of determining the impedance. Moreover, the Applicant has not disclosed that determining an impedance by way of a phase determination provides an advantage, is used for a particular purpose, or solves a stated problem.

### ***Response to Arguments***

9. Applicant's arguments with respect to claim have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 5,836,990 to Li discloses a method and apparatus for determining electrode/tissue contact.

US Patent No. 3,347,223 to Pacela discloses an impedance pneumograph with a bipolar and tetrapolar mode selector.

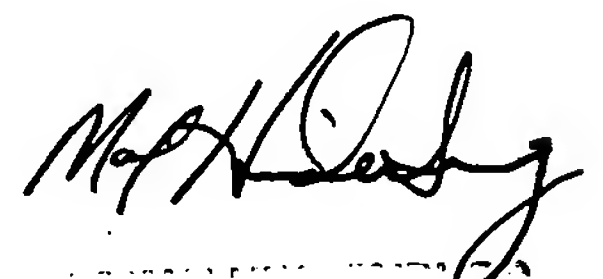
US Patent No. 6,546,270 to Goldin et al. discloses a multi-electrode catheter, system and method.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information in regards to the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTT



Max Hindenburg  
Supervisor  
Rene Towa  
Examiner